Meynier relates to a nipple shield that includes a flared or enlarged portion which fits closely by suction upon the mother's breast, and a nipple receiving portion which is integral centrally with the enlarged portion and which is of substantially the same size internally as the natural nipple. The nipple is provided with one or more openings at its outer end for the passage of fluid therefrom.

Pall relates to a device and method for depleting the leukocyte content of whole blood and products derived therefrom. The Pall device includes a fibrous leukocyte adsorption/filtration filter contained in a housing that defines a fluid flow path between an inlet and an outlet. In use, blood is drawn from a donor into a collector bag, where it is centrifuged and the plasma and platelets decanted, leaving packed red cells. The packed red cells are then forced to pass through the filter under pressure.

Pall also teaches that some viruses (*e.g.*, cytomegalovirus, Graft virus, HIV, and HTLV1) are transmitted during blood transfusions, and, since "several" of these viruses reportedly reside in the leukocytes, removing leukocytes from packed red cells is beneficial to prevent viral infection by transfused blood. Michie discloses that retroviruses including HIV-1, HTLV-1, and HTLV-2 are transmitted by breast milk.

Rather than substantively responding to the July 23, 2007 Request for Reconsideration, the PTO has merely cited *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007), for "foreclos[ing] the argument that a specific teaching, suggestion or motivation is required to support a finding of obviousness." Office Action at page 3. However, the PTO's reliance on *KSR* is insufficient to sustain this rejection for at least three reasons.

First, although a *specific, express* suggestion or motivation in the cited art is not required to support a finding of obviousness, there still has to have been some reasonable expectation that known elements could be combined as claimed: "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield *predictable* results." 127 S. Ct., at 1739, 82 U.S.P.Q.2d, at 1395. "[W]hen a patent 'simply arranges old elements with each performing *the same function it had been known to perform*' and yields *no more than one would expect* from such an arrangement, the combination is obvious." 127 S. Ct., at 1740, 82 U.S.P.Q.2d, at 1395–6. "[A] court must ask whether the improvement is

more than the *predictable* use of prior art elements *according to their established functions*." 127 S. Ct., at 1740, 82 U.S.P.Q.2d, at 1396. The PTO's own examination guidelines also make this clear: "[T]he focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on what such a person *would have reasonably expected to have been able to do* in view of that knowledge." "Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*," Official Gazette Notice (Nov. 6, 2007), http://www.uspto.gov/go/og/2007/week45/patgide.htm. "[C]ombining known prior art elements is not sufficient to render the claimed invention obvious *if the results would not have been predictable* to one of ordinary skill in the art." *Id.*

The skilled artisan would not have reasonably expected that the Pall filter could be used with the Meynier nipple shield to filter leukocytes from breast milk, because this combination would be more than simply the predictable use of prior art elements according to their established functions. Specifically, the established function of the Pall filter is to filter leukocytes from *packed red cells* under *high pressure*. In contrast, the present invention used a filter to filter leukocytes from *breast milk* under *relatively low pressure*. Thus, the filter of Pall and the filter of the present invention function differently.

Regarding the difference in pressure, as noted in the Request for Reconsideration filed July 23, 2007, Pall teaches that liquids with surface tensions lower than the critical wetting surface tension ("CWST") of a medium will wet the medium and, if the medium has through pores, will flow through it readily. Liquids with surface tensions higher than the CWST of the medium will not flow at all at low differential pressures, but will do so if the pressure is raised sufficiently. The greater the difference between the surface tension of the fluid, the greater the amount of pressure required to induce flow.

With the Pall filter, blood is drawn from a donor into a collector bag. The collector bag is placed in a centrifuge and spun, forming packed red cells at the bottom of the bag. The collector bag is then placed in a plasma extractor, decanting the plasma and most of the platelets, and leaving packed red cells in the bag. These packed red cells are then forced to pass through the Pall filter using pressure from a pressure cuff or the plasma extractor at an exemplary pressure of about 0.4 Kg/cm^2 (*i.e.*, about 294.22 mmHg).

In contrast, with the Meynier nipple shield (and the nipple shield of the present invention) breast milk is drawn directly from the mother to the baby, using nothing but suckling to draw the fluid through the nipple shield. However, the average suckling pressure in humans is only about 50 mmHg, and the maximum suckling pressure is less than 200 mmHg. Prieto et al., "Sucking Pressure and Its Relationship to Milk Transfer During Breastfeeding in Humans," *J. Reprod. Fertil.* 108:69–74, abstract (1996) (of record). This is far lower than the pressure taught by Pall. The PTO has failed to explain why, given Pall's teaching regarding the need for "forcing" the fluid through the filter, one of skill in the art would have expected that the filter of Pall could be used under lower pressure conditions.

As for the difference in the fluid being filtered, Pall teaches that it is highly undesirable in a leukocyte depletion device to use a medium with a CWST more than about 15 to about 20 dynes/cm lower than the liquid's surface tension. Since none of the cited references discloses the surface tension of breast milk, the skilled artisan would not have been able to determine from these references whether the Pall filter could be used to filter breast milk at all, let alone whether one could do so with the Pall filter attached to the Meynier nipple shield.

For all of these reasons, there would have been no reasonable expectation that the filter of Pall could be combined with the Meynier nipple shield to filter leukocytes from breast milk.

Second, *KSR* confirms that "when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR v. Teleflex*, at 12 (citing *U.S. v. Adams*, 383 U.S. 39, 51–52 (1966)); *id.* at 22. The cited references teach away from combining the filter of Pall with the nipple shield of Meynier.

As noted in the Request for Reconsideration, the Meynier nipple shield is the same size internally as the natural nipple, which averages around 16 mm during lactation, Ramsay et al., "Anatomy of the Lactating Human Breast Redefined with Ultrasound Imaging," *J. Anat.* 206:525–34 (2005) (of record). Pall, however, discloses filter devices that have in internal diameter of around 47.6 mm or 88.6 mm, at least nearly triple the diameter of the Meynier nipple shield. Furthermore, Pall teaches that a large cross sectional area perpendicular to the flow path

of the filtered fluid is desirable to prevent clogging, which teaches away from using the Pall filter in smaller diameter devices.

In addition, Michie teaches away from filtering breast milk. Michie states that "one *might conceivably* remove cell associated virus by filtering breast milk." This passage has been previously cited by the PTO as teaching the removal of virus by filtering breast milk. It does not. Not only is this language speculative at best, according to Michie, filtering monocytes from breast milk would not prevent virus transmission. In particular, Michie teaches that retroviruses, although present in milk monocytes, are also found free in milk solution, and that removing cell associated virus by filtering would not eliminate free viral particles. Thus, Michie does not teach that filtering out virus-associated cells would remove virus from breast milk. Instead, Michie suggests pasteurization, vaccination, nevirapine treatment, establishing pasteurized milk banks, and wet nursing practices as possible solutions to vertical viral transmission by breast feeding.

The PTO has failed to explain why, despite this teaching away by Pall and Michie, it would nevertheless have been obvious to one of ordinary skill in the art to combine the filter of Pall with the Michie nipple shield.

Finally, *KSR* confirms that "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusions of obviousness." *KSR* at 14 (citing *In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006)). The PTO has failed to do so.

In particular, in the office action mailed April 23, 2007, the PTO took the position that it would have been obvious to modify the nipple shield of Meynier to include a leukocyte filter to remove leukocytes from breast milk to prevent transmission of HIV viruses to an infant as allegedly suggested by Pall and Michie. Thus, the rejection for obviousness rested on the PTO's position that Pall, Michie, and Meynier provided a reason to combine the Pall filter with the Meynier nipple shield. The present office action provides no additional basis for this rejection. The July 23, 2007 Request for Reconsideration demonstrated that Pall, Michie, and Meynier (alone or in combination) do not provide a motivation to filter leukocytes from breast milk and, therefore, there would have been no motivation to attach a leukocyte filter to the Meynier nipple shield. In addition, it demonstrated that none of the cited references (alone or in

combination) teaches or suggests a nipple shield of the present invention. To maintain this rejection, the PTO must either explain why, despite the deficiencies identified in the previous Request for Reconsideration, Pall, Michie, and Meynier nevertheless teach the present invention, or articulate an alternative basis for the rejection. The PTO has not done either of these things. This alone renders the present rejection improper.

For all of the these reasons, the rejection of claims 1–6 for obviousness over Meynier, Pall, and Michie is improper and should be withdrawn.

In view of all of the foregoing, it is submitted that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

Date: February 22, 2008

/Shelley A. Jones/
Shelley A. Jones
Registration No. 53,081

NIXON PEABODY LLP
1100 Clinton Square
Rochester, New York 14604-1792
Telephone: (585) 263-1461
Facsimile: (585) 263-1600